

al. (WO 98/48814). The Examiner contends that it would have been obvious to use a mucoretentive composition comprising colloidal particles of silicon dioxide, as claimed by Applicant, based on the teachings of the *Silicol* advertisement and Banning et al. Applicant respectfully traverses this rejection.

The *Silicol* product is a gel that comprises water and colloidal silicic acid (also known as colloidal silicon dioxide), and according to the *Silicol* advertisement the *Silicol* product forms a soothing coating over the lining of the stomach and intestines. The *Silicol* product, however, fails to comprise 1) a select pharmaceutical active, 2) citric acid or a salt thereof, or 3) a select pharmaceutical active and citric acid or a salt thereof in combination with colloidal particles of silicon dioxide.

Banning et al. disclose aqueous pourable liquid compositions, and a method of administering the compositions, wherein the compositions comprise sodium alginate and an alkali metal bicarbonate. Banning et al. further disclose that the compositions can form a protective coating on gastrointestinal mucosal tissue, and can be used as vehicles for targeted delivery of pharmaceutical active compounds. Banning et al., however, fail to disclose a mucoretentive composition, or a method of administering the composition, wherein the composition comprises colloidal particles of silicon dioxide and citric acid or colloidal particles of silicon dioxide and citric acid in combination with a select pharmaceutical active.

Applicant submits that the *Silicol* product in view of Banning et al. would not obviously lead the skilled artisan to a realization of Applicant's invention of Claims 36, 38-39, 41-46, and 48. The *Silicol* product fails to teach or suggest a mucoretentive composition comprising a pharmaceutical active or citric acid. Banning et al. fail to teach or suggest a mucoretentive composition comprising colloidal particles of silicon dioxide or citric acid. By contrast, Applicant's Claims 36, 38-39, 41-46, and 48 are directed to a mucoretentive composition comprising colloidal particles of silicon dioxide in combination with a select pharmaceutical active and citric acid or a salt of citric acid.

The Examiner contends that since Banning et al. disclose mucoretentive compositions that can comprise a pharmaceutical active and since the *Silicol* product comprises water and colloidal particles of silicic acid, then it would be prima facie obvious to the skilled artisan to formulate a mucoretentive composition comprising colloidal particles of silicon dioxide in combination with a pharmaceutical active. Applicant disagrees. Applicant submits that the *Silicol* product provides no motivation for the skilled artisan to look for an art citation such as Banning et al. for the teaching or suggestion of a mucoretentive composition comprising a pharmaceutical active, prima facie or otherwise. In fact, the *Silicol* advertisement teaches and suggests that the *Silicol* product should be taken at least one hour before or after the intake of medications, thus providing no motivation to use the *Silicol* product in combination with a pharmaceutical active.

Moreover, the *Silicol* product nor Banning et al. teaches or suggests a mucoretentive composition comprising citric acid or a salt thereof as claimed by Applicant. Therefore a mucoretentive composition comprising water, colloidal silicon dioxide, and a pharmaceutical active would still be deficient in teaching or suggesting Applicant's mucoretentive composition that is an aqueous

mucoretentive composition that comprises colloidal particles of silicon dioxide, a select pharmaceutical active, and citric acid or a salt of citric acid.

In view of the foregoing remarks, it is submitted that the *Silicol* product in view of Banning et al. fails to teach or suggest an oral, mucoretentive pharmaceutical composition, and method of administering the composition, as recited in Applicant's Claims 36, 38-39, 41-46, and 48. Rejection of these claims as being unpatentably obvious over the *Silicol* product in view of Banning et al. is improper and, therefore, should be withdrawn.

Conclusions

Applicant has made an earnest effort to place his application in proper form and to distinguish his claimed invention from the applied prior art. WHEREFORE, reconsideration of this application, withdrawal of the rejection under 35 U.S.C. 103(a), and allowance of Claims 36, 38-39, 41-46, and 48 are respectfully requested.

Respectfully submitted,

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